DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 27, 2015

Intuit Medical Products, LLC
Mr. Jack Griffis
Vice President, R&D
6018 Eagles Rest Trail
Sugar Hill, Georgia 30518

Re: K143738
Trade/Device Name: Dillard Sinuplasty Balloon Catheter
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: July 28, 2015
Received: July 29, 2015

Dear Mr. Griffis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: *DSS* Balloon Catheter

Indications for Use:

The *DSS* Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

510(k) Number: _____

Date Prepared: December 28th, 2014

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:
Intuit Medical Products (IMP), LLC
6018 Eagles Rest Trail
Sugar Hill, Georgia 30518

B. Company Contact:
Jack Griffis
Vice President, Research & Development
(404) 583-6889 (direct)
jgriffis@intuitmedicalproducts.com

C. Device Information:
Trade Name: Dillard Sinuplasty System *(DSS)*
Common Name: Sinus Balloon Catheter

D. Classification: Ear, Nose, and Throat Manual Surgical Instrument
LRC, 21 CFR 874.4420

E. Predicate Device(s):
Acclarent Relieva® and Relieva Acella Sinuplasty Balloon Catheter, K073041
Acclarent Relieva® Solo Sinuplasty Balloon Catheter, K111254

F. Physical Description:
The *DSS* Balloon Catheter is a flexible catheter that is intended to dilate the sinus ostia. The device is compatible with commonly used accessories including standard guide wires, guide cannulas and inflation devices. Catheter working length is from 25cm up to 140cm and is available in both over-the-wire (large diameter balloons) and rail configurations (small diameter configurations).

The distal end of the catheter includes a balloon that expands to known diameters and lengths at specific pressures. The balloon has radiopaque markers to assist with radiographic positioning. The proximal end of the device is a common catheter design consisting of a plastic hub and strain relief. The hub is used to inflate the balloon and the luer connector integrated into the hub is compatible with standard inflation devices. A second lumen within the catheter, intended for guidewire use, extends from either a rapid exchange style distal port just proximal to the balloon (small diameter configurations) or through the central lumen back to the proximal hub (large diameter configurations) and through the distal tip. The *DSS* Balloon Catheter is supplied sterile and intended for single use.

G. Indications for Use:

The *DSS* Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

H. Comparison of Characteristics / Performance Testing / Substantial Equivalence:

The *DSS* Balloon Catheter is substantially equivalent to the predicate devices in intended use, indications for use, fundamental scientific technology, and important performance specifications. The device was subjected to the following performance tests to support the assertion of substantial equivalence*:*

- Dimensional Verification
- Balloon Rated Burst Pressure (RBP)
- Balloon Fatigue
- Balloon Inflation and Deflation
- Catheter Joint Bond Strengths
- Biocompatibility Testing in Compliance with the ISO 10993-1 and the FDA Bluebook Memorandum (G-95) as follows:
  - Cytotoxicity
  - Sensitization (Guinea Pig Maximization)
  - Irritation and (Acute) Systemic Toxicity
  - Material-mediated Pyrogenicity

No new questions of safety or effectiveness were identified during device testing; therefore, the *DSS* Balloon Catheter is considered substantially equivalent to the predicate devices.

Jack Griffis
Vice President, Research & Development

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